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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/380,885	09/07/99	CURATOLO W	PC9824AJTJ

HM12/1226

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EXAMINER	
SHAREH, S	
ART UNIT	**PAPER NUMBER**
1619	9

DATE MAILED: 12/26/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/380,885	Curatolo et al
Examiner	**Group Art Unit**
Shahnam Sharareh	1619

☒ Responsive to communication(s) filed on *Nov 20, 100*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-53* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-53* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Amendment filed on October 30, 2000 has been entered.

1. Applicant's arguments with respect to the rejection of claims 1, 6, 10, 11, 14 under 35 U.S.C. 102(b) as being anticipated by Ranade US Patent 4,803,076 have been considered but are not found persuasive.

Applicant argues that Ranade teaches devices exhibiting delayed release, and that Ranade's device exhibits first order sustained release of sertraline. Applicant also argues that Ranade does not teach a controlled release device that exhibits delayed release followed by immediate release.

In response Examiner draws Applicant attention to the recitation of claim 1. The instant claims are directed to a delayed dosage form comprising sertraline and an acceptable carrier. There is no indication or limitations for first or zero order kinetics or release of sertraline. Ranade disclose Sertraline tablets coated with similar carriers as the instant utilized carriers; therefore, such composition is able to meet the funcitonal limitaitons of the instant claims, because the are made of similar components. In addition, Examiner disagrees with Applicant in his assertion that Ranade's invention is directed toward devices. Examples 1-2 of Ranade is directed to controlled release tablets, not devices. Further Ranade clearly claims tablet dosage forms, *claims 10-15.* Mere allegations of non-equivalence does not overcome the prior art. Examiner inadvertently did not include claim 9 in this rejection in the Office Action filed on April 19, 2000. However, Ranade also meets the limitation of claim 9. Accordingly, claims 1, 6, 9-11, 14 stand rejected

2. Applicant's argument with respect to the rejection under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Pfizer Inc WO 92/02212 were fully considered but are not found persuasive.

Applicant argues that Herbig does not teach an initial period of delay engineered into the device which following the initial delay period, effects immediate release of the remaining active ingredient. Applicant also argues that the cellulose acetate of Herbig is used for a different purpose and thus is not a pH-sensitive structure.

In response Examiner states that the pending composition claims are solely directed to sertraline and a suitable carrier. Herbig teaches such combination. Thus, their compositions can inherently meet such functional limitations as argued by Applicant. Further, the intended use of a component such as hydroxymethylcellulose in a composition must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If prior art teaches such component, then said component is capable of performing the functional limitation thereof, in the instant case being pH-sensitive. Applicant has not met his burden of showing the difference between the prior art and the instant claimed invention. Claims 1-53 stand rejected for the reasons of record.

3. Applicant's arguments with respect to the rejection under 35 U.S.C. 103(a) as being unpatentable over Bechgaard et al EP 0080341, in view of the teachings of Drug Facts and Comparisons have been fully considered but are not found persuasive.

Applicant argues that prior to this invention the art did not disclose that sertraline side effects were locally medicated and thus could offer no expectation of success that delayed release sertraline as defined in the instant claims would treat such side effects.

In response to applicant's argument that the locally mediated side effects were not known in the art, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). As shown in the Drug Facts and Comparisons, Sertraline is associated with gastrointestinal side effects which as recognized in the art is best alleviated by enteric coating of the compound to create a delayed release dosage form. Therefore, there is motivation in the art to coat sertraline. Further, Optimizing the concentration of coating material to facilitated disintegration at a desirable pH is well within skill level of an ordinary artisan. Accordingly, claims 1-53 stand rejected.

New Grounds of Rejection

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-53 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-105 of copending Application No. 09/380,897. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claimed inventions are directed to delayed release sertraline dosage forms and methods of use thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 1-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perry et al US Patent 6,066,643 and Bechgaard et al EP 0080341, in view of the teachings of Drug Facts and Comparison..

Perry et al teach sertraline composition made with pH sensitive polymers, *col 2 lines 4-50.* Perryl also suggest the use of sertraline in the form of delayed release dosage forms, *col 6 lines 13-60.* Perry indicates that forming a delayed release formation of the active components such as sertraline is well known in the art, *col 6 lines 58-61.*

The teachings of Bechagaard and Drug Facts and Comparison is discussed before. Accordingly, although Perry et al did not specifically indicate that delayed dosage formulations of Sertraline alleviates its gastrointestinal side effects, one of ordinary skill in the art would have been motivated to prepare a delayed release form of sertraline using the pH sensitive polymers

taught by Perry and then coating the tablet according to Bechagaard, because such methods are conventional as stated by Perry. Further, as taught by Facts, an ordinary skill in the art would be motivated to decrease the gastrointestinal side effects of Sertraline by creating a delayed dosage form.

Conclusion

No claims were allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh, PharmD whose telephone number is (703) 306-5400. The examiner can normally be reached on Monday to Friday from 8:30 a.m. to 5:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on 703-308-2328. The fax phone number for this Group is 703-308-4556. Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is 703-308-1235.

sjs 12/20/2000

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